## Fetroja® (cefiderocol) – New indication

- On September 28, 2020, Shionogi announced the FDA approval of Fetroja (cefiderocol), in patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP), caused by the following susceptible Gram-negative microorganisms: *Acinetobacter baumannii* complex, *Escherichia coli*, *Enterobacter cloacae* complex, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*.

- Fetroja is also approved in patients 18 years of age or older for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Enterobacter cloacae* complex.

- The approval of Fetroja for the new indication was based on a randomized, double-blind study in 298 hospitalized adults with HABP/VABP. Patients received Fetroja or meropenem. The primary endpoint was day 14 all-cause mortality. The study also evaluated clinical cure, which was defined as resolution or substantial improvement in signs and symptoms associated with pneumonia, such that no additional antibacterial therapy was required for the treatment of the current infection through the test of cure (TOC) visit.

    — Day 14 all-cause mortality was 12.4% and 12.2% for Fetroja and meropenem, respectively (treatment difference: 0.2, 95% CI: -7.2, 7.7; non-inferiority met).
    — Clinical cure rates were 64.8% and 66.7% for Fetroja and meropenem, respectively (treatment difference: -2.0, 95% CI: -12.5, 8.5).

- The most common adverse reactions (≥ 4%) with Fetroja use for HABP/VABP were elevations in liver tests, hypokalemia, diarrhea, hypomagnesemia, and atrial fibrillation.

- The recommended dose of Fetroja for HABP/VABP and cUTIs is 2 grams administered every 8 hours by intravenous (IV) infusion over 3 hours in adults with a creatinine clearance of 60 to 119 mL/min. The recommended duration of treatment with Fetroja is 7 to 14 days. The duration of therapy should be guided by the patient's clinical status.